PUBLIC HEALTH REPORT

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A Clinical Laboratory Improvement Program for California Laboratories

IN RECENT YEARS, professional, technical and popular publications have vigorously criticized the performance of the nation's clinical laboratories, making charges ranging from unreliability of laboratory tests to outright fraud. Concern over these criticisms is reflected in the passage of recent Congressional legislation regulating laboratories in interstate commerce and in the Medicare program.

Demands for improvement of clinical laboratory performance can be met. We now have well-developed techniques for measuring and evaluating the quality of laboratory performance by means of intralaboratory quality control and proficiency testing.

Intralaboratory quality control consists of continuous surveillance by the laboratory director and his staff of all factors which may influence the reliability of test results. Basic features include the use of standards of known content in calibrating equipment, and monitoring the daily testing activities. Properly performed, quality control provides daily information concerning the reliability of the results and performance of laboratory instruments.

Proficiency testing involves the examination by the laboratory of "unknown" specimens prepared and submitted by an outside organization. The results are then submitted to the outside organization, which compares them with results achieved on the same specimens by reference or other participating laboratories. Proficiency testing shows how performance in a laboratory compares with that of reference or peer laboratories. For the state agency, it can also indicate what laboratories may be in most need of improvement, where training is needed and what subject areas require better methods.

Medicare regulations require that all independent laboratories (about 600 in California) maintain an intralaboratory quality control program acceptable to the state agency which administers state and federal laws applying to clinical laboratories — the State Health Department in California. And approximately 300 of these independent laboratories whose directors cannot meet certain requirements must participate in a state-operated or state-approved proficiency testing program. To implement these requirements, the department approved testing services developed by such professional organizations as the American Association of Bioanalysts and the College of American Pathologists.

Recently, laboratories and professional associations in this state have exerted pressures to establish uniform state laboratory laws by applying quality control and proficiency testing procedures to all laboratories as a condition of licensure. At present, however, application of quality control and proficiency testing techniques is largely voluntary.

California's physicians have fostered high standards of clinical laboratory performance for many decades. Physicians, laboratory directors and technologists began to participate in voluntary systems of laboratory certification in 1923. Long before the enactment of federal laws, they inspired and supported California's Clinical Laboratory Act of 1938, which made this state one of the few having comprehensive laws regulating clinical laboratories and setting standards. Laws and standards are still in effect, although they have been revised since that time.

State law requires that all clinical laboratories except those operated by the federal and state governments or by an individual physician for his own patients, must be licensed by the State Health Department. Currently there are 1,480 licensed laboratories in the state, of which approximately 500 are in hospitals.

The department annually conducts two rigorous examinations for laboratory personnel licenses, and has held as many as 30 workshops a year in specific areas of laboratory work. In September of this year, over 600 persons attended seminars in laboratory performance evaluation on two successive days in eight different locations in the state, under the sponsorship of the California Committee on Training in Medical Laboratory Sciences and in cooperation with professional societies and the State Health Department.

Three advisory committees assist the department's Division of Laboratories: an Advisory Committee on Clinical Laboratory Technology, concerned with education and experience standards of laboratory personnel and the legal aspects of the clinical laboratory law; an Advisory Committee on Clinical Laboratory Performance Evaluation, which assists in establishing standards for quality control and proficiency testing; and a committee to coordinate all state-wide training of laboratory personnel.

In the near future adequate controls must be established with respect to the use of automated laboratory equipment which will require more skill and education on the part of laboratory personnel. Automation will coincide with increased numbers of determinations which laboratories will be asked to run for multiphasic and single-category screening programs, especially in conjunction with increased emphasis on preventive medicine.

In the knowledge that well-tested techniques for assessing quality and maintaining high standards of laboratory services are available, the practicing physician should insist upon technical excellence in his clinical laboratory. He should also be aware of testing programs which can improve performance and control the quality of laboratory work in his office laboratory and should apply the same standards as are applied in other clinical laboratories, hospital and independent, in the state.

Physicians can in this way continue to contribute to improvement of clinical laboratory standards and performance which have made laboratory results in this state among the most consistently reliable anywhere in the nation, offering protection to physicians and patients alike.

CARDIAC ARREST AND DEPRESSED pH

"I have a strong hypothesis which is purely a theory, but I've not yet had it disproved: cardiac arrest cannot be induced with a normal pH in the absence of a gross overdose of something like fluothane. . . . Virtually all of the acute origin of cardiac arrest is superimposed upon a circulatory status in which pH is already depressed. . . . We have not yet found an individual with a normal pH in whom the heart could be arrested.

"The values for central venous blood pH are very predictable. In an operating room or in an awake patient, they are virtually never under 7.3, and a useful figure for your memory is that anything under 7.3 is abnormal. It's not very abnormal, but it's not normal, and it indicates that something is awry. . . . We use pH values as a screening mechanism: as long as the numbers are above 7.3, the situation is usually satisfactory; when they drop below this point, we start looking for a reason."

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